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Attorneys for Defendants eVenus Pharmaceuticals Laboratories, Inc. and Jiangsu Hengrui Pharmaceuticals Co., Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PACIRA PHARMACEUTICALS, INC., and PACIRA BIOSCIENCES, INC. Plaintiffs, v. eVenus PHARMACEUTICALS LABORATORIES, INC. and JIANGSU HENGRUI MEDICINE CO., LTD., a Chinese Pharmaceutical Co., Defendants.	:	Civil Action No. 2:21-cv-19829-MCA

DEFENDANTS' ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants eVenus Pharmaceuticals Laboratories, Inc. ("eVenus") and Jiangsu Hengrui Pharmaceuticals Co., Ltd.[1] ("Jiangsu Hengrui") (collectively, "Defendants") hereby answer the Complaint for patent infringement of Plaintiffs Pacira Pharmaceuticals, Inc. and Pacira BioSciences, Inc. (collectively, "Pacira" or "Plaintiffs"), as follows:

NATURE OF THE ACTION

1. Defendants admit that Plaintiffs purport to bring this action under the Food and Drug Laws and Patent Laws of the United States. Defendants further admit that eVenus owns Abbreviated New Drug Application ("ANDA") No. 214348 that was submitted to the Food and Drug Administration ("FDA") seeking approval to manufacture, use, offer for sale, sell, and/or import a generic version of EXPAREL® (bupivacaine liposome injectable suspension, 266 mg/20 mL (13.3 mg/mL)), NDA No. 022496, prior to the expiration of U.S. Patent No. 11,033,495 ("the '495 patent" or "the patent-in-suit"). Except as expressly admitted, Defendants deny the remaining allegations of Paragraph 1.

PARTIES

2. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 2 and therefore deny them.

3. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 3 and therefore deny them.

4. Defendants admit that eVenus Pharmaceuticals Laboratories, Inc. is a corporation

[1] On May 11, 2021, Jiangsu Hengrui Medicine Co., Ltd. changed its name to Jiangsu Hengrui Pharmaceuticals Co., Ltd. This Answer is submitted on behalf of Jiangsui Hengrui Pharmaceuticals Co., Ltd.

organized and existing under the laws of the State of New Jersey, having a principal place of business at 506 Carnegie Center, Suite 100, Princeton, New Jersey 08540. Defendants admit that eVenus is in the business of selling, and distributing generic drugs for the U.S. market. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 4.

5. Defendants admit that Jiangsu Hengrui Pharmaceuticals Co., Ltd. is a corporation organized and existing under the laws of China with its principal place of business at No. 7 Kunlunshan Road, Lianyungang Eco & Tech Development Zone, Lianyungang, Jiangsu 222002, China. Defendants admit that Jiangsu Hengrui's business includes manufacturing, marketing, selling, and distributing generic drugs for the U.S. market, including through its subsidiary, eVenus. Defendants admit that Jiangsu Hengrui is the holder of Drug Master File ("DMF") No. 34900, bupivacaine base. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 5.

6. Defendants admit that eVenus is a wholly owned subsidiary of Jiangsu Hengrui. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 6.

7. Defendants admit that eVenus notified Pacira by a letter dated September 30, 2021 that eVenus had submitted to the FDA ANDA No. 214348 (the "eVenus ANDA") for a generic version of bupivacaine liposome injectable suspension, 266 mg/20 mL (13.3 mg/mL) (the "eVenus ANDA Product"), seeking FDA approval to engage in the commercial manufacture, use, safe, offer for sale, and/or importation of the eVenus ANDA Product in or into the United States prior to the expiration of the '495 patent. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 7.

8. Defendants admit that they participated together in preparing and filing the eVenus ANDA pursuant to Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and

Cosmetic Act ("Paragraph IV Certifications") with the FDA. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 8.

9. Defendants admit that both eVenus and Jiangsu Hengrui were involved in the preparation of the eVenus ANDA and the eVenus Notice Letter. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 9.

10. As the eVenus ANDA Product has not yet been approved, Defendants have no present intention concerning the eVenus ANDA Product after approval and on that basis deny the allegations of Paragraph 10. The remainder of Paragraph 10 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations.

11. As the eVenus ANDA Product has not yet been approved, Defendants have no present intention concerning the eVenus ANDA Product after approval and on that basis deny the allegations of Paragraph 11. The remainder of Paragraph 11 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations.

JURISDICTION AND VENUE

12. Defendants repeat and reallege their answers to Paragraphs 1-11 of the Complaint.

13. Paragraph 13 states legal conclusions to which no answer is required. To the extent a response is required, Defendants admit that Plaintiffs purport to base subject matter jurisdiction on 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 13.

14. Defendants admit that eVenus is incorporated in New Jersey and has its primary place of business in New Jersey, at 506 Carnegie Center, Suite 100, Princeton, New Jersey 08540. The remainder of Paragraph 14 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 14.

15. Paragraph 15 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations.

16. Defendants admit that eVenus is a pharmaceutical company engaged in the distribution and sale of generic drugs in the United States. The remainder of Paragraph 16 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 16.

17. Defendants admit that eVenus is registered as wholesaler with the State of New Jersey's Department of Health under Registration No. 5004028. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 17.

18. Defendants admit that eVenus is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0400276509. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 18.

19. Defendants admit that eVenus is incorporated under the laws of New Jersey and has a place of business in New Jersey. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. The remainder of Paragraph 19 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in

Paragraph 19.

20. Defendants admit that eVenus is a wholly owned subsidiary of Jiangsu Hengrui. The remainder of Paragraph 20 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 20.

21. Defendants admit that Jiangsu Hengrui is a pharmaceutical company engaged in the development, manufacture, marketing, distribution, and sale of generic drugs. The remainder of Paragraph 21 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 21.

22. Defendants admit that eVenus is a wholly owned subsidiary of Jiangsu Hengrui. The remainder of Paragraph 22 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 22.

23. Defendants admit that Jiangsu Hengrui was involved in the preparation of the eVenus ANDA and the eVenus Notice Letter. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the ’495 patent, either directly or indirectly. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 23.

24. The allegations of Paragraph 24 contain legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 24.

25. Defendants admit that eVenus is a wholly owned subsidiary of Jiangsu Hengrui. The remainder of Paragraph 25 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 25.

26. Defendants admit that Jiangsu Hengrui consented to jurisdiction in New Jersey

in *Janssen Prods., L.P. v. eVenus Pharma. Labs. Inc.*, No. 20-cv-9369 (D.N.J.), for the purposes of that matter only.

27. Paragraph 27 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 27.

28. Paragraph 28 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 28.

29. Paragraph 29 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 29.

30. Paragraph 30 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations.

THE PATENT-IN-SUIT

31. Defendants admit that the face of the ’495 patent states that it was issued on June 15, 2021 and is entitled “Manufacturing of Bupivacaine Multivesicular Liposomes.” Defendants also admit that the face of the ’495 patent lists as inventors Jeffrey S. Hall, David J. Turnbull, John J. Grigsby, Jr., Souroush M. Ardekani, Paige N. Davis, Louie D. Garcia, Stephanie M. Kurz, and Kathleen D. A. Los and that Exhibit A purports to be a copy of the patent. Defendants deny that the patent was duly and legally issued. To the extent any further response is required, Defendants deny the remaining allegations.

32. Paragraph 32 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations.

33. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 33 and therefore deny them. The remainder of Paragraph 33 contains legal conclusions to which no response is required. To the extent a response is required,

Defendants deny the remaining allegations.

34. Defendants admit that the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") entry for New Drug Application ("NDA") No. 022496 for bupivacaine liposome injectable suspension, 266 mg/20mL (13.3 mg/mL), sold under the trade name EXPAREL®, currently lists the expiration of the '495 patent as January 22, 2041. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 34 and therefore deny them. The remainder of Paragraph 34 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations.

THE EXPAREL® DRUG PRODUCT

35. Defendants admit that the Orange Book entry for NDA No. 022496 for bupivacaine liposome injectable suspension, 266 mg/20mL (13.3 mg/mL), sold under the trade name EXPAREL®, lists Pacira Pharmaceuticals, Inc. as the applicant. Defendants further admit that Plaintiffs purport to attach a true and correct copy of the prescribing information for EXPAREL® as Exhibit B. The remainder of Paragraph 35 contains no allegations of fact directed at Defendants, and therefore requires no response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 35 and therefore deny them.

36. Paragraph 36 contains no allegations of fact directed at Defendants, and therefore requires no response. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 36 and therefore deny them.

37. Defendants admit that the ’495 patent is listed in the Orange Book with respect to EXPAREL®. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 37 and therefore deny them. The remainder of Paragraph 37 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations.

DEFENDANTS’ ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

38. Defendants admit that Defendants submitted eVenus’s ANDA to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the eVenus ANDA Product, prior to the expiration of the ’495 patent. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 38.

39. Defendants admit that the FDA has not yet approved eVenus’s ANDA. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 39.

40. Defendants admit that, in the eVenus Notice Letter, eVenus notified Pacira of the submission of eVenus’s ANDA to the FDA. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 40.

41. Defendants admit that, in the eVenus Notice Letter, eVenus acknowledged that the Reference Listed Drug for eVenus’s ANDA is EXPAREL®. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 41.

42. Defendants acknowledge that, in the eVenus Notice Letter, eVenus notified Pacira that, as part of its ANDA, eVenus had filed a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the ’495 patent. Except as expressly admitted,

Defendants deny the remaining allegations in Paragraph 42.

43. Defendants admit that, as part of the eVenus ANDA, Defendants filed certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '495 patent, asserting that certain claims of the '495 patent are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation of the eVenus ANDA Product. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 43.

44. Defendants admit that, in the eVenus Notice Letter, eVenus stated that the eVenus ANDA Product contains bupivacaine as an active ingredient. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 44.

45. Defendants admit that eVenus's submission of the eVenus ANDA was based upon the use of Jiangsu Hengrui's DMF. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 45.

46. Defendants admit that they were involved in the preparation of the eVenus ANDA. The remainder of Paragraph 46 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 46.

47. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 47 and therefore deny them. The remainder of Paragraph 47 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 47.

COUNT I – INFRINGEMENT OF THE '495 PATENT

48. Defendants repeat and reallege their answers to Paragraphs 1-47 of the Complaint.

49. Defendants admit that Defendants submitted the eVenus ANDA to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the eVenus ANDA Product, prior to the expiration of the '495 patent. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 49.

50. Defendants deny that the eVenus ANDA Product will infringe any valid and/or enforceable claim of the '495 patent. Paragraph 50 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the allegations in Paragraph 50.

51. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. Paragraph 51 contains legal conclusions to which no response is required. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 51.

52. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. Paragraph 52 contains legal conclusions to which no response is required. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 52.

53. Paragraph 53 contains legal conclusions to which no response is required. To the extent any further response is required, Defendants deny the remaining allegations in Paragraph 53.

54. Defendants deny that the eVenus ANDA Product will infringe any valid and/or enforceable claim of the '495 patent, either directly or indirectly. Paragraph 54 contains legal conclusions to which no response is required. To the extent a response is

required, Defendants expressly deny the allegations in Paragraph 54.

55. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. The remainder of Paragraph 55 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the remaining allegations in Paragraph 55.

56. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. The remainder of Paragraph 56 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 56.

57. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. The remainder of Paragraph 57 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the remaining allegations in Paragraph 57.

58. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. The remainder of Paragraph 58 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the remaining allegations in Paragraph 58.

59. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. The remainder of Paragraph 59 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the remaining allegations in Paragraph 59.

60. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. The remainder of

Paragraph 60 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the remaining allegations in Paragraph 60.

61. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. The remainder of Paragraph 61 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the remaining allegations in Paragraph 61.

62. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. The remainder of Paragraph 62 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the remaining allegations in Paragraph 62.

63. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. The remainder of Paragraph 63 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '495 PATENT

64. Defendants repeat and reallege their answers to Paragraphs 1-63 of the Complaint.

65. Paragraph 65 states legal conclusions to which no answer is required. To the extent a response is required, Defendants deny the remaining allegations in Paragraph 65.

66. Paragraph 66 contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations.

67. Defendants admit that eVenus submitted eVenus's ANDA to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, offer to sell,

or sale within the United States or importation into the United States of the eVenus ANDA Product, prior to the expiration of the '495 patent. Except as expressly admitted, Defendants deny the remaining allegations in Paragraph 67.

68. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. Paragraph 68 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the allegations in Paragraph 68.

69. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. To the extent a further response is required, Defendants deny the remaining allegations in Paragraph 69.

70. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. Paragraph 70 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the allegations in Paragraph 70.

71. Paragraph 71 contains legal conclusions to which no response is required. To the extent any further response is required, Defendants deny the remaining allegations in Paragraph 71.

72. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. Paragraph 72 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the allegations in Paragraph 72.

73. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. Paragraph 73

contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the allegations in Paragraph 73.

74. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. Paragraph 74 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the allegations in Paragraph 74.

75. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. Paragraph 75 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the allegations in Paragraph 75.

76. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. Paragraph 76 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the allegations in Paragraph 76.

77. Defendants expressly deny that the eVenus's ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. Paragraph 77 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the allegations in Paragraph 77.

78. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. Paragraph 78 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the allegations in Paragraph 78.

79. Defendants admit that, as part of the eVenus ANDA, Defendants filed Paragraph

IV certifications with respect to the '495 patent, asserting that certain claims of the '495 patent are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation of the eVenus ANDA Product. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. The remainder of Paragraph 79 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the remaining allegations in Paragraph 79.

80. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. Paragraph 80 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the allegations in Paragraph 80.

81. Defendants expressly deny that the eVenus ANDA Product infringes any valid and/or enforceable claim of the '495 patent, either directly or indirectly. Paragraph 81 contains legal conclusions to which no response is required. To the extent a response is required, Defendants expressly deny the allegations in Paragraph 81.

PLAINTIFF'S PRAYER FOR RELIEF

The remainder of Plaintiff's Complaint recites a prayer for relief to which no response is required. To the extent that a response is required, Defendants deny that Plaintiff is entitled to any remedy or relief, including those requested.

AFFIRMATIVE DEFENSES

Without any admission as to the burden of proof, burden of persuasion, or the truth of any allegation in Plaintiff's Complaint, and expressly reserving their right to assert additional

defenses, Defendants state the following affirmative defenses:

First Affirmative Defense

The manufacture, use, sale, offer for sale, or importation of the eVenus ANDA Product will not infringe, directly or indirectly, any valid or enforceable claim of the '495 patent.

Second Affirmative Defense

The filing of the eVenus ANDA has not infringed, and will not infringe, directly or indirectly, any valid or enforceable claim of the '495 patent.

Third Affirmative Defense

The claims of the '495 patent are invalid for failure to satisfy the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 256, and 287, and/or the doctrine of obviousness-type double patenting.

Fourth Affirmative Defense

The Complaint fails to state a claim for willful infringement.

Fifth Affirmative Defense

Defendants' actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Sixth Affirmative Defense

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff eVenus Pharmaceuticals Laboratories, Inc. ("eVenus," "Defendant") asserts the following counterclaims against

Plaintiffs/Counterclaim-Defendants Pacira Pharmaceuticals, Inc. and Pacira BioSciences, Inc. (collectively, "Pacira"):

PARTIES

1. eVenus Pharmaceutical Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 506 Carnegie Center, Suite 100, Princeton, New Jersey, 08540.

2. On information and belief, Pacira Pharmaceuticals, Inc. is a corporation organized and existing under the laws of California, with its principal place of business at 5 Sylvan Way, Suite 300, Parsippany, New Jersey 07054. On information and belief, Pacira Pharmaceuticals, Inc. is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, and distributing pharmaceutical drugs for the U.S. market.

3. On information and belief, Pacira BioSciences, Inc. is a corporation organized under the laws of Delaware with its principal place of business at 5 Sylvan Way, Suite 300, Parsippany, New Jersey 07054. On information and belief, Pacira Biosciences, Inc. is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, and distributing pharmaceutical drugs for the U.S. market.

JURISDICTION AND VENUE

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. The Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Pacira because Pacira has availed itself of the rights and privileges, and has subjected itself to the jurisdiction, of this forum by suing eVenus and Jiangsu Hengrui,and/or because Pacira conducts substantial business in, and has regular and systematic contacts with, this District.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

FIRST CLAIM FOR RELIEF

(Declaratory Judgment Of Noninfringement Of The '495 Patent)

8. Defendant reasserts and realleges Paragraphs 1-8 of Defendant's Counterclaims as if fully set forth herein.

9. The manufacture, use, sale, offer for sale, and/or importation of bupivacaine liposome injectable suspension, 266 mg/20 mL (13.3 mg/mL), that is the subject of eVenus's ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '495 patent.

10. There is an actual, substantial, and continuing justiciable case or controversy between Defendant and Pacira of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Defendant's non-infringement of the '495 patent.

11. Defendant is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of bupivacaine liposome injectable suspension, 266 mg/20 mL (13.3 mg/mL), that is the subject of eVenus's ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '495 patent, either directly or indirectly.

SECOND CLAIM FOR RELIEF

(Declaratory Judgment Of Invalidity Of The '495 Patent)

12. Defendant reasserts and realleges each of Paragraphs 1-12 of Defendant's Counterclaims as if fully set forth herein.

13. The claims of the '495 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and 112 and/or the doctrine of obviousness-type double patenting.

14. There is an actual, substantial, and continuing justiciable case or controversy between Defendant and Pacira of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the '495 patent.

15. Defendant is entitled to a judicial declaration that the claims of the '495 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Defendant requests judgment in its favor and against Pacira:

A. declaring that the manufacture, use, sale, offer for sale, and/or importation of bupivacaine liposome injectable suspension, 266 mg/20 mL (13.3 mg/mL), that is the subject of the eVenus ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '495 patent, either directly or indirectly;

B. declaring that the claims of the '495 patent are invalid;

C. ordering that judgment be entered in favor of Defendant and Pacira's Complaint be dismissed with prejudice;

D. declaring this case exceptional and awarding Defendant its reasonable attorney

fees and costs of defending this action and prosecuting their counterclaims under 35 U.S.C. § 285; and

E. awarding Defendant such other and further relief as the Court may deem just and proper.

Dated: January 6, 2021

Respectfully submitted,

/s *Eric I. Abraham*

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